DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g1356d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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May 22, 2001 *

WARNING LETTER

NWE-22-01W

VIA FEDERAL EXPRESS

Willard Nelson, President
The Foredom Electric Co.
Route 6
16 Stoney Hill Road
Bethel, Connecticut 06801

Dear Mr. Nelson:

During an inspection of your establishment located on Payne Road in Bethel, Connecticut, on January 10, 2001, our investigator determined that your establishment manufactures a Model 973 Powered Percussor. Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), a "percussor" is considered to be a device because it is used to treat a medical condition or to affect the structure or function of the body. Powered Percussors are classified in Title 21 of the Code of Federal Regulations (CFR) in Part 868, Section 5665 (21 CFR 868.5665), and are intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage.

The above-stated inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21 CFR, Part 820, as follows:

1. Failure to establish and maintain a Quality System that is appropriate for the above device that meets the Quality System Requirements.

* Reissued 5/25/01 with Title

The Foredom Model 973 Percussor (the device) is a "prescription" (Rx) device and the law requires that it comply with the requirements of 21 CFR 801.109 (enclosed).

Our investigation shows that the device label fails to bear the following statement required by 21 CFR 801.109(b)(1):"Caution: Federal law restricts this device to sale by or on the order of a _____", the blank to be filled in with the word "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by law of the State in which he practices to use or order the use of the device. (See additional discussion below regarding an allowable alternate prescription labeling statement.) In addition, the labeling ("Operation and Service Manual") for the device fails to bear "indications" for its use, required by 21 CFR 801.109(c). Furthermore, our investigation shows that your firm is not distributing the device only to persons who are licensed practitioners or to persons who have a prescription or other order from a licensed practitioner to purchase the device, as required by 21 CFR 801.109(a)(2). See related discussion below. Because the device does not meet these requirements, it is in violation of the law. In legal terms, the device is misbranded under Section 502(f)(1) of the Act for failure to bear adequate directions for use.

FDA, in its enforcement discretion, will not object to the use of the statement "Rx only" as an alternative to the prescription device labeling statement above required by 21 CFR 801.109(b)(1). The symbol statement "Rx only" does not necessarily need to be bracketed in quotation marks, and the word "only" may appear in upper or lower case letters, for example Rx only, Rx Only, or Rx ONLY. The statement shall be prominent and conspicuous, whether by font size, the use of capital letters, or bold print, as described in section 502(c) of the Act and the related regulatory requirements for medical devices labeling found 21 CFR 801.15 (enclosed).

In order to continue distributing the device as a "percussor", you need to (1) add the referenced caution statement or "Rx only" to the label on the device package (i.e., the immediate container), (2) add the indications to the labeling for the device (e.g., the Operation and Service Manual), and (3) limit sales to licensed practitioners or persons who have a prescription or other order from such practitioners. The indication should have wording similar to that identified above for 21 CFR 868.5665.

Our investigation reveals that some of the persons to whom your firm distributes the device are not licensed practitioners or do not have the referenced prescription or other order to purchase the device, and these persons are using the device as a "massager". A massager is also a device under the Act. Therapeutic massagers are classified in 21 CFR 890.5660. A massager is not a prescription device, and can be distributed without a prescription, which we refer to as being sold Over the Counter (OTC).

The law requires that the label of the device bear the device's common or usual name. While a label on the device does identify the device as a "percussor", it does not identify it as a "massager" or "therapeutic massager" for the referenced OTC sales. Because the device does not meet this requirement, it is in violation of the law. In legal terms, the device is misbranded under Section 502(e)(4) of the Act for failure to bear its common or usual name.

In addition, the law requires that device labeling bear the intended use(s) and directions for use. These requirements are not met for the OTC sales of the device as massager. Because the device does not meet these requirements, it is in violation of the law. In legal terms, the device is again misbranded under Section 502(f)(1) of the Act for failure to bear adequate directions for use.

To continue distributing the device as a "massager" to persons who are not licensed practitioners or who do not have a prescription or other order to purchase the device as referenced above, your firm must develop a second and new set of labeling for the device just for these sales. For these sales you need to (1) identify the device in the label as a "massager", a "therapeutic massager", or similar wording (but not as a "percussor"), (2) identify the intended uses as a massager (see below) in the device labeling (instruction manual), and (3) provide directions for use as a massager in the labeling (instruction manual). The intended uses as a massager must be limited to the following, and for any other claims your firm will need to obtain marketing clearance from FDA as described in the enclosed materials:

1. Relaxes muscles locally;

2. Temporarily increases local blood circulation; and

3. Temporarily relieves minor muscular aches, pain, and tension caused by fatigue or overexertion.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the implementing regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventative action on your Quality System.

It is necessary for you to take action on these matters now. Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you

have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce, R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

Gail P. Costello
District Director
New England District Office

Enclosures: As stated